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PATENT

Case No. 8627/096 (PA-5245-RFB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of)
Fred T. Parker) Art Unit: 3775
Serial No.: 09/815,567) Examiner: Anuradha Ramana
Filed: March 23, 2001) Confirmation Number: 6497
For: INTRODUCER SHEATH)

REPLY BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
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This Reply Brief is in response to the Examiner's Answer dated October 8, 2008. The underlying appeal is taken from the decision of the Examiner dated February 1, 2008, finally rejecting claims 1-13, 15-20, 22 and 23.

As indicated previously, the present invention is directed to a flexible, kink-resistant, introducer sheath. The sheath has an outer tubular member having a greater flexibility at the distal end portion than at a proximal portion.

Introducer sheaths are well known for percutaneous vascular access. Such sheaths can be of thin-walled construction, and are prone to kinking as they pass through the body vessel. When a sheath kinks in a body vessel, the sheath is unusable and must be removed from the patient. Increasing the thickness of the

sheath only minimally improves the level of kink resistance, while at the same time undesirably enlarging the entry hole and/or reducing the diameter of the lumen of the sheath.

A prior art introducer sheath with improved kink resistance was disclosed by the present inventor in U.S. Patent No. 5,380,304. Generally speaking, this prior art sheath comprises a coil having a plurality of coil turns fitted around an inner lubricious tube. As indicated in the specification and the figures of the '304 patent, there is a uniform spacing between the coil turns. See, e.g., Col. 4, lines 9-11, and Figs. 2-4. An outer tube is connected to the inner tube through the uniform spacings of the coil turns. The outer tube comprises a heat-formable polyamide material, such as nylon, for connecting with an outer surface of the inner tube, between the coil turns. The patent also discloses a sheath distal tip portion of the same durometer, or harder, than the durometer of the outer tube. The distal tip portion is thermally bonded to a tapered distal end of the outer tube. This prior art sheath is illustrated at Figs. 1 and 2 of the present application, and is discussed, e.g., at page 2, lines 1-18, and at page 3, line 26 to page 4, line 29 of the present application.

The distal tip member in the prior art structure is provided to facilitate entry into the percutaneous access site. Although a sheath having a high durometer tip is effective for facilitating entry into many percutaneous access sites, such tips are not desirable in all instances. For example, when a tortuous path through the body must be traversed, or when highly sensitive treatment sites must be accessed, a softer, more flexible distal tip portion may be desired.

As stated in the Brief of Appellant, independent claim 1 of the present application is directed to a flexible, kink-resistant introducer sheath (10). The sheath comprises an inner tube (12) extending to a distal end, and a wire coil (14) wound around the inner tube and extending to an end spaced proximally from the inner tube distal end. The wire coil comprises a plurality of uniformly spaced coil turns. (Figs. 3, 4) A first outer tube (20) is disposed around the wire coil and the inner tube therewithin to a first outer tube distal end spaced proximally from the wire coil distal end such that a distal end portion of the wire coil extends distally therebeyond. At least a second outer tube (22) is disposed around the wire coil and the inner tube

therewithin extending distally from the first outer tube distal end and covering the distal end portion of the wire coil and extending slightly beyond the distal end of the inner tube. The first outer tube is formed of a material having a relatively hard durometer, and the second outer tube is formed of a material of a substantially softer durometer than the material of the first outer tube. (Page 5, lines 1-21; Figs. 3-6)

Independent claim 22 is directed to a flexible, kink resistant introducer sheath (10). The sheath comprises an inner tube (12) extending to a distal end. A wire coil (14) is wound around the inner tube, and extends to a wire coil distal end spaced proximally from the inner tube distal end. The wire coil comprises a plurality of uniformly spaced coil turns, each coil turn being free from crossing by another coil turn. (Figs. 3, 4) A first outer tube (20) is disposed around the wire coil and the inner tube to a first outer tube distal end spaced proximally from the wire coil distal end. A second outer tube (22) extends distally from the first outer tube distal end. The second outer tube is disposed around and covers the distal end portion of the wire coil and the inner tube, and extends slightly therebeyond. The first outer tube is formed of a material having a relatively hard durometer, and the second outer tube is formed of a material of a durometer softer than the durometer of the first outer tube. (Page 5, lines 1-21; Figs. 3-6)

Independent claim 23 is directed to an introducer sheath (10). The introducer sheath comprises an inner tube (12) extending to a distal end, and a wire coil (14) wound around the inner tube and extending to an end spaced proximally from the inner tube distal end. The wire coil comprises a plurality of coil turns, each turn being free from being interwoven with another coil turn. (Figs. 3, 4) A first outer tube (20) is disposed around the wire coil and the inner tube to a first outer tube distal end spaced proximally from the wire coil distal end. At least a second outer tube (22) is disposed around the wire coil and the inner tube extending distally from the first outer tube distal end and covering the distal end portion of the wire coil. The first outer tube is formed of a material having a relatively hard durometer, and the second outer tube is formed of a material having a softer durometer than the material of the first outer tube. (Page 5, lines 1-21; Figs. 3-6)

REPLY**Issue 1.**

Claims 1-2, 4-5, 10-13, 15-20, 22 and 23 are not unpatentable under 35 U.S.C. §103(a) over Horrigan et al. in view of Park et al.

At page 7 of her Answer, the Examiner rebuts the arguments raised by Appellant in his Brief by stating that that the test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, "what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413 208 USPQ 871 (CCPA 1981)."

Appellant appreciates the Examiner's reference to the *In re Keller* case, because the cited passage from this case briefly and succinctly summarizes Appellant's position herein. For example, in the discussion concerning Issue 1 in his Brief, Appellant went to great pains to point out what the combined teachings of the cited references would have suggested to those of ordinary skill in the art, and to explain why the skilled artisan upon review of such references would not reach the conclusions espoused by the Examiner. Appellant repeatedly emphasized, with both argument and evidence, that those skilled in the art recognize that there is a distinct difference between various types of reinforcements utilized in medical devices. As emphasized by Appellant, a teaching that simply describes in passing the use of a certain reinforcement, or another that discusses the possibility of using a variety of reinforcements under conditions in which the particular type of reinforcement is of little significance to the teaching at hand, does not provide a skilled artisan with sufficient guidance to arrive at the invention claimed herein, absent the use of hindsight when the claimed invention is used as a template. (See, e.g., Declaration of Thomas A. Osborne, paragraphs 6, 7; Declaration of Sathya Kaliyamoorthy, PhD, paragraphs 11-13).

It is true that the secondary Park reference indicates that various types of reinforcements may be used with his inventive catheter. However, it must be recognized that the invention in Park related to the use of a super-elastic material as a forming (e.g., reinforcing) material, wherein the material is capable of self-forming

upon exposure to heat to a desired second form from a first form. The fact that Park's teaching could be used with a device having a coil, a braid, or a "braided coil" reinforcement was of little consequence to the particular invention described in the reference. According to Park, the benefits of the invention (utilizing the self-forming member) could be achieved with a plethora of different types of reinforcements.

It is wrong to suggest that this teaching of Park establishes the "equivalence" of the various reinforcements, as stated by the Examiner. Contrary to the Examiner's assertions (Examiner's Answer, pages 4, 8 and 9), Park neither teaches nor suggests the alleged equivalence of various reinforcements as claimed by the Examiner ("It is the Examiner's position that Park et al teach the equivalence of a braid or a coil or a combination of one or more of each for reinforcement of an intravascular device for use in an environment of increasingly small diameters..." Answer, page 9). This broad interpretation of the Park teaching is both astonishing, and unfounded. It is clear that Park teaches no such thing. Further, the declarations submitted by Appellant directly refute the Examiner's contentions.

In light of the guidance provided by the *In re Keller* case cited by the Examiner in her Answer (that the test of obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art), it is helpful to briefly revisit the following statements concerning the Park citation made by Appellant in his Brief:

There is no teaching or suggestion of equivalence or interchangeability in general between such reinforcements, nor is the patent even concerned with making such a comparison. It is clear that Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, or vice versa. In fact, Park provides no reasons why one skilled in the art would ever want to use a coil reinforcement instead of a braid. In this vein, the teaching of Park is consistent with Horrigan, which also provides no reasons why an artisan would ever want to use a coil reinforcement.

Although Park indicates that his device exhibits (among numerous other cited properties) a certain amount of kink resistance in some circumstances (Col. 2, lines 40-44), this teaching must be read in the context of the

invention that he espouses, namely a catheter having a self-formable tip. In view of Park's stated preference for a braid in his preferred embodiments, one skilled in the art would be led away from the present invention, by erroneously assuming that a braided reinforcement provides better kink resistance than a coil reinforcement. This contention has already been rebutted in the Kaliyamoorthy and Osborne Declarations. Simply put, Appellant submits that one skilled in the art would not reach the conclusions espoused by the Examiner concerning the alleged equivalency and/or interchangeability between a braid and a coil upon a review of the Park patent.

Brief of Appellant, page 11.

For at least the foregoing Appellant respectfully submits that the combined teachings of the cited references would not have suggested the present invention to those of ordinary skill in the art. In fact, it is more likely than not that the cited references would have led the skilled artisan away from the teachings of the present invention.

Issues 4 and 5.

Claims 1-13, 15-20 and 22 are not unpatentable under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. Claims 1-13, 15-20 and 22 are not unpatentable under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These rejections are both based upon the same issue, namely, the Examiner's contention that it is not clear how the spacing between the "uniformly spaced" coil turns is measured. In her Answer, the Examiner belatedly even includes an illustration not previously presented in this prosecution to support her position.

Appellant respectfully submits that it has long been held that the written description is judged from the viewpoint of one of ordinary skill in the art. *Wang Labs Inc. v Toshiba Corp*, 993 F. 2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993). A patent specification must only set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed, and to recognize that the inventor

invented what is claimed. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886, 1896 (Fed. Cir. 2004).

Further, in evaluating the sufficiency of the written description, terms need not be found *in haec verba*. *Koito Mfg. Co. v. Turn-Key-Tech LLC*, 381 F.3d 1142, 72 USPQ2d 1190, 1199 (Fed. Cir. 2004). In *Koito Mfg. Co.*, the Court of Appeals for the Federal Circuit held that the written description requirement need not necessarily be satisfied by words in the text, but also may be satisfied by figures and diagrams. In the present context, it is clear that Figs. 3-4 illustrate a sheath having uniformly spaced coil turns.

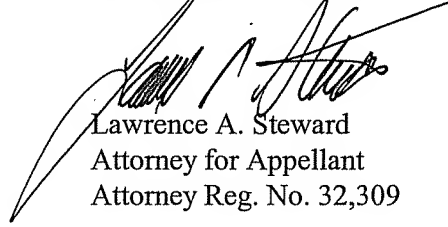
In the present case, one need only look at Fig. 2 of the present application, which is identified in the specification as the introducer sheath of prior art United States Patent No. 5,380,304. According to the description of the '304 patent, the coil turns have uniform spacing. Col. 4, lines 9-11. It is apparent that the uniform spacing between the coil turns of the inventive sheaths depicted in Figs. 3 and 4 of the present application is virtually identical to the spacing of the sheaths depicted in Fig. 2 of the prior art sheath.

Clearly, when the written description is judged from the viewpoint of one of ordinary skill in the art, it is clear that the present patent specification sets forth sufficient detail to allow a person of ordinary skill in the art to understand what is claimed in the present application.

CONCLUSION

For at least the foregoing reasons, as well as the reasons previously presented in the Brief of Appellant, Appellant respectfully submits that the grounds for the Examiner's rejections of claims 1-13, 15-20, 22 and 23 are not well taken, and should be reversed by this Board.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A flexible, kink-resistant introducer sheath comprising:
an inner tube extending to a distal end;
a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of uniformly spaced coil turns;
a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends distally therebeyond; and
at least a second outer tube disposed around said wire coil and said inner tube therewithin extending distally from said first outer tube distal end and covering said distal end portion of said wire coil and extending slightly beyond said distal end of said inner tube,
said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a substantially softer durometer than said material of said first outer tube.
2. The introducer sheath according to claim 1, wherein said first and second outer tubes are bonded to each other and to said wire coil, and to said inner tube between windings of said wire coil.
3. The introducer sheath according to claim 2, wherein an outwardly facing surface of said inner tube has been roughened to enhance bonding thereto of said first and second outer tubes.
4. The introducer sheath according to claim 2, wherein said bonding is heat bonding.

5. The introducer sheath according to claim 1, wherein a radiopaque marker band is affixed to said wire coil distal end within said second outer tube.

6. The introducer sheath according to claim 1, wherein said second outer tube is polymeric and contains radiopaque filler.

7. The intravascular sheath according to claim 6, wherein said second outer tube contains between about 20% and 85% by weight of radiopaque filler particles.

8. The introducer sheath according to claim 6, wherein said second outer tube contains about 80% by weight of radiopaque filler particles.

9. The introducer sheath according to claim 1, wherein said first outer tube is substantially free of radiopaque filler.

10. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of at least 5 D lower than that of the material of the first outer tube.

11. The introducer sheath according to claim 10, wherein said first outer tube comprises a material having a durometer of about 56D to 58D.

12. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of between about 10D and 75D.

13. The introducer sheath according to claim 12, wherein said second outer tube comprises a material having a durometer of about 39D.

14. (canceled)

15. The introducer sheath according to claim 1, wherein said wire coil comprises flat wire.

16. The introducer sheath according to claim 1, wherein a distal tip region of the sheath is arcuate.

17. The introducer sheath according to claim 16, wherein said arcuate distal tip region has a length of about 1 cm or more.

18. The introducer sheath according to claim 16, wherein said arcuate distal tip region extends about an angle of about 90°.

19. The introducer sheath according to claim 1, wherein said wire coil extends for a length of about five millimeters beyond said distal end of said first outer tube.

20. The introducer sheath according to claim 1, wherein said inner tube is unitarily formed.

21. (canceled)

22. A flexible, kink resistant introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to a wire coil distal end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of uniformly spaced coil turns, each coil turn being free from crossing by another coil turn;

a first outer tube disposed around said wire coil and said inner tube to a first outer tube distal end spaced proximally from said wire coil distal end; and

a second outer tube extending distally from said first outer tube distal end and disposed around and covering said distal end portion of said wire coil and said inner tube and extending slightly therebeyond;

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a durometer softer than the durometer of the first outer tube.

23. An introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of coil turns, each turn being free from being interwoven with another coil turn;

a first outer tube disposed around said wire coil and said inner tube to a first outer tube distal end spaced proximally from said wire coil distal end; and

at least a second outer tube disposed around said wire coil and said inner tube extending distally from said first outer tube distal end and covering said distal end portion of said wire coil, said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material having a softer durometer than said material of said first outer tube.

IX. EVIDENCE APPENDIX

Appended to the Brief of Appellant are two Rule 1.132 declarations cited in this Brief, and relied upon by Appellant.

The appended Declaration of Thomas A. Osborne was attached to Applicant's Response filed on April 29, 2004, and entered into the record of this case on May 3, 2004. This Declaration was referenced in the Office Action of June 29, 2004.

The appended Declaration of Sathya Kaliyamoorthy was attached to Applicant's Response filed on April 24, 2007, and entered into the record of this case on April 24, 2007. This Declaration was referenced in the Office Action of September 11, 2007.

X. RELATED PROCEEDINGS APPENDIX

None.